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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,088	12/11/2003	Gregory L. Sundberg	279.646US1	7977
21186 7590 01/10/2008 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER SMITH, TERRI L	
			ART UNIT 3762	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/734,088

Applicant(s)

SUNDBERG, GREGORY L.

Examiner

Terri L. Smith

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-810-14, 2123-27, 29, 30 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10-14, 30, 35-42 and 2729 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 2123-26 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 December 2007 has been entered.

### *Response to Arguments*

2. Applicant's arguments with respect to claims 1-3, 5-7, 21, 23-26 and 43 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

3. Additionally, Applicant's arguments filed on 17 December 2007 have been fully considered but they are not persuasive. Applicant's arguments that because Gardeski et al., U.S. Patent 7,130,700 and Cross, Jr. et al., U.S. Patent 5,935,159 do not recite one or more fillers radially extending less than 360 degrees from a first end to a second end, as recited in Applicant's claim 1, Gardeski et al. and Cross, Jr. et al. do not anticipate such claim are moot because Applicant's specification does not recite said limitation either.

Similarly, Applicant's arguments that regarding claim 2, Applicant cannot find in Gardeski et al. and Cross, Jr. et al. any recitation of one or more filler recesses which include "non-occupied recesses, the non-occupied recesses providing compression features" to the lead are moot as well because Applicant's specification does not recite said limitations either.

In the same way, Applicant's arguments that because Gardeski et al. and Cross, Jr. et al. do not recite the combination of a tubular body and one or more fillers to form a single isolated

lumen, as recited in Applicant's claim 43, Gardeski et al. and Cross, Jr. et al. do not anticipate such claim are moot once again because Applicant's specification does not recite said limitation either.

Consequently, it is the Examiner's position that Applicant has added new matter to claims 1, 2, 26 and 43 and, as a result, said claims will be rejected herein below under 35 U.S.C. § 112 1<sup>st</sup> paragraph.

Applicant's argument that the combination of Cross, Jr. and Gardeski teach away from the Applicant's claimed combination of an outer surface portion of a cable conductor contacting an outer surface portion of a coiled conductor such that the conductors are electrically independent, the asserted combination of references is improper and fails to establish all elements recited in claim 26 is not persuasive. It is the Examiner's position that only the portion of the insulated wire in the distal segment 80 (as cited by the Applicant from Gardeski et al. at column 10, lines 35–38) is stripped of its insulation, and that the insulation is not stripped from the entire wire as alleged by the Applicant. Therefore, the wires would be electrically insulated from each other where the insulation remains in tact. Consequently, claim 26 will remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Cross, Jr. in view of Gardeski as set forth in the Office Action mailed on 05 June 2007.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1–3, 5–7, 21, 23–26 and 43 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification, in combination with the other elements in the claims, is

one or more fillers “radially extending less than 360 degrees from a first end to a second end”(claim 1) and

one or more filler recesses which include “non-occupied recesses, the non-occupied recesses providing compression features” to the lead (claim 2) and

that the at least one cable conductor and the coiled conductor are electrically independent (claim 26) and the combination of a tubular body and one or more fillers to form a single isolated lumen (claim 43).

Examiner is unable to find any recitation or teaching in the written description of Applicant’s specification of any of the new matter listed herein above. Should Applicant argue that the drawings of Applicant’s specification disclose the limitations of claims 1, 2 and 43, the Examiner will likewise argue that the art of record also discloses said limitations in the drawings of their specification as well.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 5, 6 and 23, are rejected under 35 U.S.C. § 102(e) as being anticipated by Belden, U.S. Patent Application Publication 2004/0064174.

8. Regarding claims 1, 6, 23, Belden discloses an implantable lead (e.g., FIGS. 1, 5A, 5B, 6A and 6B, where FIG. 1 shows the implantable lead body at element 10) comprising: a tubular lead body including an inner body surface and an outer body surface (e.g., element 12); a least one electrode disposed along a tubular lead body (e.g., element 16);

at least one conductor electrically coupled with at least one electrode (e.g., paragraph [0025], lines 9–10), at least one conductor including one or more layers of insulation (e.g., element 52); and

one filler generally C-shaped (e.g., FIG. 7, element 44-sizing member; paragraph [0040]) disposed within a tubular lead body, one filler radially extending within an inner body surface less than 360 degrees from a first end to a second end including one recess extending from an inner perimeter portion thereof (e.g., paragraph [0041]);

wherein one or both of the first or second filler ends are disposed adjacent to an insulated at least one conductor (e.g., FIG. 8A elements 44 and 45-conductor).

9. With respect to claim 5, Belden discloses a coiled conductor (e.g., FIGS. 4 and 5A; element 40) forming a lumen therein (element 42), a coiled conductor disposed within a lead body (e.g., paragraph [0032]), and a coil conductor longitudinal axis is offset from a lead body

longitudinal axis (e.g., FIG. 6B, element 72c being a coiled conductor as described in paragraph [0032]).

10. Regarding claim 43, Belden discloses a tubular body and one filler combine to form a single isolated lumen for insertion of at least one insulated conductor (e.g., FIGS. 1 and 8A, elements 12 being interpreted as the tubular body, element 44 being interpreted as the filler, element 28 being interpreted as the isolated lumen and element 45-insulated conductor as described in paragraph [0033] and is a coiled conductor as described in paragraph [0032], line 10).

11. Claims 1–3, 5–7, 23 and 24 are rejected under 35 U.S.C. § 102(e) as being anticipated by Gardeski et al., U.S. Patent 7,130,700.

12. Regarding claims 1, 3, 23 and 24, Gardeski et al. disclose a tubular body including an inner body surface and an outer body surface (e.g., TITLE; FIGS. 2 and 7, where FIG. 7 shows and active fixation element 112-pacing tip electrode); at least one electrode disposed along a tubular lead body (e.g., element 42);

at least one conductor electrically coupled with at least one electrode (column 4, lines 18–20; column 6, lines 36–40; column 8, lines 1–5), at least one conductor including one or more layers of insulation (e.g., column 15, lines 13–15); and

one filler generally C-shaped disposed within a tubular lead body (e.g., FIG. 8, element 134, being interpreted as a filler, 121-groove portion, being interpreted as generally C-shaped),

one filler radially extending within an inner body surface less than 360 degrees from a first end to a second end (e.g., where elements 138f-outward extending member is being

interpreted as a first end radially extending within an inner body surface and 138g-outward extending member is being interpreted as a second end radially extending within an inner body surface and these outward extending members are less than 360 from each other)

including one recess extending from an inner perimeter portion thereof (e.g., element 119-groove portion);

wherein one or both of the first or second filler ends are disposed adjacent to an insulated at least one conductor (e.g., element 154).

13. With respect to claim 2, Gardeski et al. disclose one recess includes non-occupied recesses providing compression features (e.g., the recess defined between outward extending members 138a and 138b).

14. Regarding claim 5, Gardeski et al. disclose a coiled conductor (e.g., element 156) forming a lumen therein (e.g., element 157), and a coil conductor longitudinal axis is offset from a lead body longitudinal axis (e.g., in FIG. 8, element 157 is offset from the longitudinal axis of 160-central lumen).

15. With respect to claim 7, one filler is formed of silicone (e.g., column 14, lines 54–56).

16. Claims 1, 3, 5–7, 23–25 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cross Jr. et al., 5,935,159.

17. Regarding claims 1, 3, 6 and 23, Cross Jr. et al. disclose a tubular body including an inner body surface and an outer body surface (e.g., FIGS. 1, 7 and 12, where FIG. 7 shows and active fixation element 112-pacing tip electrode); at least one electrode disposed along a tubular lead body (e.g., element 16);



at least one conductor (e.g., element 216) electrically coupled with at least one electrode, at least one conductor including one or more layers of insulation (e.g., element 218); and

one filler generally C-shaped disposed within a tubular lead body (e.g., element 204 and 402, being interpreted as a filler, and the inner surface as it radiates out toward the outer insulative tube 200 of said elements being interpreted as generally C-shaped),

one filler radially extending within an inner body surface less than 360 degrees from a first end to a second end (e.g., where the ends of the radiated portions of elements 204 and 402 are being interpreted as a first end and second end radially extending within an inner body these ends of these radiating portions that touch the insulative tube 200 that encloses the conductors are less than 360 from each other)

including one recess extending from an inner perimeter portion thereof (e.g., FIG. 8, the recess that encloses the insulated conductor);

wherein one or both of the first or second filler ends are disposed adjacent to an insulated at least one conductor (e.g., element 216 and 218 and 408 and 410).

18. With respect to claims 5, 7, 24 and 25, Cross, Jr. et al. disclose a coiled conductor forming a lumen (claim 5) (e.g., elements 418 and 420); one or more fillers is formed of silicone (claim 7) (e.g., column 3, lines 13–15); an active fixation assembly (claim 24) (e.g., column 5, line 11); insulation include at least one of PTFE or polyurethane (claim 25) (column 3, lines 25–26).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claim 21 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gardeski et al., U.S. Patent 7,130,700.

21. Gardeski et al. disclose bending flexibility may be uniquely tailored to specific applications through careful selection of inner and outer insulating member materials (e.g., column 7, lines 13–15, wherein the inner insulating member having been cited as the one or more fillers herein above), but not explicitly a flexibility of one or more fillers is greater than a flexibility of a tubular body. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the inner insulating member as taught by Gardeski et al., to have a flexibility greater than a flexibility of a tubular body, because Applicant has not disclosed that a flexibility of one or more fillers is greater than a flexibility of a tubular body provides an advantage, is used for a particular purpose, or solves a stated problem.

One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the flexibility of the inner insulating member as taught by Gardeski et al., because it would have been obvious to try a flexibility of one or more fillers is greater than a flexibility of a tubular body because the material of the inner insulating member in combination with the outer insulating material is made out of the same material used by the Applicant and it is carefully chosen to enhance the flexibility of the lead to provide optimum lead handling and manipulation during implant.

Therefore, it would have been an obvious matter of engineering design choice to modify the inner insulating material to obtain the invention as specified in the claim.

22. Claim 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cross Jr. et al., 5,935,159 as applied to claim 1 above, and in view of Gardeski et al., U.S. Patent 7,130,700.

23. Cross, Jr. et al. disclose an outer surface portion of at least one conductor contacting an outer surface portion of another conductor (FIG. 7, elements 216 and 218), but not that one is a coiled conductor and one is a cable conductor. However, Gardeski et al. disclose that one is a coiled conductor and one is a cable conductor (e.g., column 15, lines 15–18) to yield the predictable result of providing an efficient, diverse, optimum and reliable lead for effective administration of therapy.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Cross, Jr. et al. to include a coiled conductor and a cable conductor, as taught by Gardeski et al. to yield the predictable result of providing an efficient, diverse, optimum and reliable lead for effective administration of therapy.

### ***Conclusion***

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on Monday - Friday between 7:30 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 3762

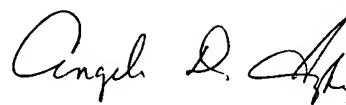
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